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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 578832000100 |
| | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/518,044 |
| INTERNATIONAL APPLICATION NO. PCT/IN2002/00207 | INTERNATIONAL FILING DATE 14 October 2002 | PRIORITY DATE CLAIMED 17 June 2002 |
| TITLE OF INVENTION A PROCESS OF MANUFACTURE OF NOVEL DRUG DELIVERY SYSTEM: MULTILAYER TABLET COMPOSITION OF THIAZOLIDINEDIONE AND BIGUANIDES | | |
| APPLICANT(S) FOR DO/EO/US Amit Krishna ANTARKAR et al. | | |

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
- ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
- ☒ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
- ☐ The US has been elected (Article 31).
- ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - ☐ is attached hereto (required only if not communicated by the International Bureau).
 - ☐ has been communicated by the International Bureau.
 - ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
- ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - ☐ is attached hereto.
 - ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
- ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - ☐ are attached hereto (required only if not communicated by the International Bureau).
 - ☐ have been communicated by the International Bureau.
 - ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - ☐ have not been made and will not be made.
- ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
- ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
- ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

- ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- ☐ A preliminary amendment.
- ☐ An Application Data Sheet under 37 CFR 1.76.
- ☐ A substitute specification.
- ☐ A power of attorney and/or change of address letter.
- ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
- ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
- ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
- ☒ Other items or information: Return Receipt Postcard

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/518,044 | | INTERNATIONAL APPLICATION NO. PCT/IN2002/00207 | | ATTORNEY'S DOCKET NUMBER 578832000100 | |
| The following fees have been submitted | | | | CALCULATIONS | PTO USE ONLY |
| 21. <input type="checkbox"/> Basic national fee \$300 | | | | \$ | |
| 22. <input type="checkbox"/> Examination fee | | | | | |
| If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) \$100 | | | | \$ | |
| All other situations \$200 | | | | \$ | |
| 23. <input type="checkbox"/> Search fee | | | | | |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 | | | | \$ | |
| International Search Report prepared and provided to the Office \$400 | | | | \$ | |
| All other situations \$500 | | | | \$ | |
| TOTAL OF 21, 22 and 23 = | | | | \$ | 0.00 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| - 100 = | /50 = | | x \$250.00 | | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)). | | | | \$ | 130.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | 20 - 20 = | | x | \$ | 0.00 |
| Independent claims | 3 - 3 = | | x | \$ | 0.00 |
| MULTIPLE DEPENDENT CLAIM(s) (if applicable) | | | + | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | 130.00 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | \$ | |
| SUBTOTAL = | | | | \$ | 130.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). | | | | + | \$ |
| TOTAL NATIONAL FEE = | | | | \$ | 130.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | + | \$ |
| TOTAL FEES ENCLOSED = | | | | \$ | 170.00 |
| 00000072 031952 10518044 | | | | Amount to be refunded: | \$ |
| 130.00 DA | | | | Amount to be charged: | \$ |
| <p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ 170.00 to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <p style="text-align: right;">SIGNATURE _____ NAME Raj S. Dave'</p> <p>CUSTOMER NUMBER: 25227</p> <p style="text-align: right;">42,465 REGISTRATION NUMBER</p> | | | | | |

08/22/2005 GFREY

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UNITED STATES PATENT AND TRADEMARK OFFICE

RSD/LSWO

 57883-A 0001.00
 UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

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| U.S. APPLICATION NUMBER NO. 10/518,044 | FIRST NAMED APPLICANT Antarkar A Krishna | ATTY. DOCKET NO. 57883200100 |
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| INTERNATIONAL APPLICATION NO. |
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PCT/IN02/00207

 25227
 MORRISON & FOERSTER LLP
 1650 TYSONS BOULEVARD
 SUITE 300
 MCLEAN, VA 22102

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| IA. FILING DATE 10/14/2002 | PRIORITY DATE 06/17/2002 |
|-------------------------------|-----------------------------|

CONFIRMATION NO. 2710

371 FORMALITIES LETTER



OC000000016306947

Date Mailed: 06/17/2005

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 12/16/2004
- Copy of the International Search Report filed on 12/16/2004
- Copy of IPE Report filed on 12/16/2004
- Oath or Declaration filed on 12/16/2004
- U.S. Basic National Fees filed on 12/16/2004
- Substitute Specification filed on 12/16/2004
- Priority Documents filed on 12/16/2004

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - The names of the inventors's are different on the declaration than on the international application. Please clarify.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity.

- \$130 Late oath or declaration Surcharge.

DOCKETED *Miss Req Due*
 REMINDER: *7/17/2005*
 DUE DATE: *8/17/2005*
 FINAL DUE DATE: *11/17/2005*

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

JOHN L ANDERSON

Telephone: (703) 308-9140 EXT 211

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/518,044 | PCT/IN02/00207 | 57883200100 |